K093449

FEB 12 2010

Mini Lap Technologies Inc.

510 (k) Summary

Submission Type:

Special 510(k)

Date Prepared [21 CFR 807.92(a)(1)]

November 2, 2009

Submitter's Information [21 CFR 807.92(a)(1)]

Regulatory Contact
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Sponsor / Manufacturer
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Tel: 914 591 8400

FDA Establishment Registration is 3007123990

Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Trade Name

- MINI LAP Retractors

Device Common, Usual, or Classification Names

- Laparoscopic Instruments, Retractors, Cannula, Trocar, Manual Surgical Instruments

Classification Panel

- Classification of this device would fall under the responsibility of the Gastroenterology / Urology panel.

Class

Based on our research we believe the device is a class 2 device classified under the following Product Codes:

- KOG, 21 CFR 876.1500, Endoscope Accessories
- KOA, 21 CFR 876.4730 Manual Surgical Instruments
- FBQ, 21 CFR 878.5090 Trocar

Predicate Device [21 CFR 807.92(a)(3)]

- Mini Lap Instruments – K070686

Description of the Device [21 CFR 807.92(a)(4)]

The MINI LAP Instruments are a family of minimally invasive devices. The devices penetrate soft tissue to access certain areas of the human anatomy. The devices are used to manipulate other soft internal tissues.

Prior to insertion, the physician must depress the safety button and retract the instrument into the needle. The needle is inserted through the soft tissue under visualization. Once the needle has penetrated the soft tissue, the physician will advance the instrument into the body cavity using the handle. As the instrument advances, the jaws of the instrument will open. The device includes a self-activating safety that prohibits the jaws from returning to their fully retracted position while in use, which acts as a blunt shield for the sharp needle tip.

The device is provided in the following configurations:

Length	Clamp Type
250mm	Retractor Fan
250mm	Retractor Rake

The devices are sterile disposable, single patient only. The devices were designed to hold pneumoperitoneum during use.

Intended Use [21 CFR 807.92(a)(5)]

The MINI LAP Instruments are a family of minimally invasive devices with the means to penetrate soft tissue to access certain areas of the human anatomy. The devices are used to manipulate other soft internal tissues..

Technological Characteristics [21 CFR 807.92(a)(6)]

We believe the MINI LAP instruments are substantially equivalent to the predicate devices.

Performance Data [21 CFR 807.92(b)(1)]

We believe the addition of these two jaw configurations are a minor expansion to a product family that already has 510(k) clearance. The subject device is composed of biocompatible materials and the sterilization process has been validated.

Conclusion [21 CFR 807.92(b)(3)]

We believe the changes are minor and conclude that the subject devices are as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mini Lap Technologies, Inc.
% Mr. Joseph Azary
80 Shelton Technology Center
Shelton, Connecticut 06484

FEB 12 2010

Re: K093449
Trade/Device Name: Mini Lap Retractors
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: January 7, 2010
Received: January 12, 2010

Dear Mr. Azary:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems

(QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: MINI LAP Retractors

Indications For Use:

The MINI LAP Instruments are a family of minimally invasive devices with the means to penetrate soft tissue to access certain areas of the human anatomy. The devices are used to manipulate other soft internal tissues.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093449